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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,565	02/04/2002	John J. Sauk	UNIMD 4	7145

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,565	SAUK, JOHN J.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,24-26 and 29-38* is/are pending in the application.

4a) Of the above claim(s) *1-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26 and 29-38* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: Exhibit 1

DETAILED ACTION

Re: Sauk J

1. The amendment filed 7/28/2006 is acknowledged and entered into the record. Accordingly, claims 20-23 and 27-28 are canceled without prejudice or disclaimer, and claims 33-38 are newly added.

2. Claims 1-19,24-26,29-38 are pending, claims 1-19 are withdrawn as being drawn to a non-elected invention.

3. Claims 24-26,29-38 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Rejections

Claim Rejections - 35 USC § 112, 1st paragraph

5. Claims 24-26,29-33, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DESCRIPTION REJECTION.

The specification teaches that there are numerous peptide sequences which can be encompassed by the claimed peptide motif of SEQ ID No: 1. Therefore, the sequence motif of SEQ ID No: 1 encompasses more that represented by sequence such as SEQ ID No: 9 and 13.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of

A motif of SEQ ID No: 1, which fails to provide one of skill in the art with a specific core peptide structure. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *University Of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The Court stated that" [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. at 1567, 43 USPQ2d at 1405. The court also stated that:

> *a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize*

> *the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.*

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. V. Gen- Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* at 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in *Lilly* and *Enzo* were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus the instant specification may provide an adequate written description of the sequence motif of SEQ ID No: 1, per *Lilly*, by structurally describing representative peptides or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per *Enzo*, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not provide one of skill in the art with a core structure of amino acids, instead, the specification provides one of skill in the art with amino acid characteristics (i.e. hydrophobic amino acids) and further attempts to characterize the peptide sequences by claiming a genus by a function alone. Therefore, the claimed sequence motif of SEQ ID No: 1 fails to satisfy either the *Lilly* or *Enzo* standards. Although the specification discloses a couple of sequences that fail within the motif, these are not representative of the broad class of peptide sequences that may fall within very large and expansive genus of peptides encompassed by the claimed sequence motif of SEQ ID No: 1. This broad recitation fails to satisfy the standard set out in *Enzo* because the specification provides no functional characteristics coupled to structural features. Further, the specification also fails to describe the broad genus of peptides encompassed the sequence motif claimed by the test set out in *Lilly* because the specification describes a limited handful of peptides (i.e. SEQ ID No: 9 and 13 for example). Therefore it fails to describe a representative number of species. Thus the specification does not provide an adequate written description of the claimed invention

that is required to practice the claimed invention.

Claim Rejections - 35 USC § 102

6. Claims 24-26,33, and 38 are rejected under 35 U.S.C. 102(b) as being anticiapted by Bayer, E (Peptides: Chem. Biochem., Proc. Amer. Peptide Symp., 1st (1970), meeting date 1968, 99-112). Bayer E teaches an isolated dodecapeptide (AFAFAFAFAFAF) -- (see abstract and attached exhibit 1) Bayer does not characterize the dodecapeptide as having the ability to bind to Hsp47 or that it is capable of generating a cytostatic or cytolytic effect on carcinoma cells, the claimed functional limitation would be an inherent property of the referenced peptide. Moreover, the dodecapeptide is nto full length collagen nor a naturally occurring collagen or fragment thereof. Finally, the dodecapeptide also contains at least one F (Phe) as claimed.

Hence, even though the claims are drawn to a peptide that acts by a specific mechanism, the claimed peptide does not appear to distinguish over the prior art teaching of the same or nearly the same product. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Conclusion

No claim is allowed. Claim 34 is objected to for depending on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
October 10, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER

Exhibit 1

differed from one another in their amino acid and hydroxy acid content and in their number of ester and amide bonds.

ACCESSION NUMBER: 75:6305 CA
TITLE: Synthesis of valinomycin analogs with modified side chains and different numbers of amide and ester groups
AUTHOR(S): Fonina, L. A.; Sanasaryan, A. A.; Vinogradova, E. I.
CORPORATE SOURCE: Inst. Khim. Prir. Soedin. im. Shemyakina, Moscow, USSR
SOURCE: Khimiya Prirodnykh Soedinenii (1971), 7(1), 69-81
CODEN: KPSUAR; ISSN: 0023-1150
DOCUMENT TYPE: Journal
LANGUAGE: Russian

L3 ANSWER 376 OF 377 REGISTRY COPYRIGHT 2006 ACS on STN
RN 26251-07-0 REGISTRY
FS PROTEIN SEQUENCE; STEREOSEARCH
SQL 12

SEQ 1 AFAFAFAFAF AF
========== ==
HITS AT: 1-12

RELATED SEQUENCES AVAILABLE WITH SEQLINK

REFERENCE 1

AB Merrifield's solid phase method dets. the sequence of synthetic peptides. Failure sequences are low, and polypeptides containing 60-80 amino acids can be synthesized. The purification of the end product is important and the dodecapeptides (Leu-Ala)6 and (Ala-Phe)6 were purified so that no failure sequences could be detected. No racemization of the amino acids occurred.

ACCESSION NUMBER: 73:56410 CA
TITLE: New results in the solid phase method for the synthesis of peptides
AUTHOR(S): Bayer, Ernst
CORPORATE SOURCE: Dep. of Cem., Univ. of Houston, Houston, TX, USA
SOURCE: Peptides: Chem. Biochem., Proc. Amer. Peptide Symp., 1st (1970), Meeting Date 1968, 99-112. Editor(s): Weinstein, Boris. Marcel Dekker, Inc.: New York, N. Y.
CODEN: 17XJA8
DOCUMENT TYPE: Conference
LANGUAGE: English

REFERENCE 2

AB Failure sequences occur during solid phase synthesis of polypeptides, but their number is considerably decreased by acetylation of the amino groups which do not react, or by the use of specially prepared resin-coated glass beads.

ACCESSION NUMBER: 72:101090 CA
TITLE: Failure sequences in the solid phase synthesis of polypeptides
AUTHOR(S): Bayer, Ernst; Eckstein, H.; Haegele, K.; Koenig, Wilfried A.; Bruening, W.; Hagenmaier, Hanspaul; Parr, Wolfgang
CORPORATE SOURCE: Dep. of Chem., Univ. of Houston, Houston, TX, USA
SOURCE: Journal of the American Chemical Society (1970), 92(6), 1735-8
CODEN: JACSAT; ISSN: 0002-7863
DOCUMENT TYPE: Journal
LANGUAGE: English

L3 ANSWER 377 OF 377 REGISTRY COPYRIGHT 2006 ACS on STN
RN 26144-26-3 REGISTRY